

Remarks

The claims are not being amended herein.

§112 Rejections

In the Office Action dated 01/25/2010, claims 1, 3, 4, 6-9, 11-24, 27-28, and 32-47 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In particular, the Office stated that the limitation in claim 1 reciting “a reservoir, wherein the reservoir contains active agent” lacked adequate support in the original disclosure. Rather than looking at the very clear §112 support provided by original claim 28, the Office instead observed how paragraph [0042] of the specification provided a definition of a device that delivers a therapeutically effective amount of an active agent from a biomaterial. The Office stated that claim 1 provided no connection between the biomaterial and the active agent. The Office appears to have felt that the device could not both have an active agent in its reservoir (per original claim 28) and deliver the active agent from a biomaterial (per paragraph [0042] and per original claim 28).

Applicant disagrees with the Office’s apparent reading of the present disclosure. As noted previously, an Applicant may rely on the original claims for §112 support. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); accord *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). Original claim 28 recited “the reservoir contains active agent.” Applicant maintains that this alone provides adequate support under §112 for the exact same limitation in amended claim 1 reciting “the reservoir contains active agent.”

The Office has in no way acknowledged the fact that original claim 28 recited “the reservoir contains active agent.” The Office has also made no attempt to reconcile its untenable position with *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) or *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); accord *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

By failing to address Applicant's reliance on original claim 28 for §112 support of the above-quoted limitation of claim 1, the Office has failed to properly observe MPEP 707.07(f). The Office's position could not be sustained on appeal. Applicant therefore respectfully requests that the rejection be withdrawn.

With respect to the Office's reliance on paragraph [0042], there is no inconsistency at all between paragraph [0042] and original claim 28. Likewise, there is no inconsistency at all between paragraph [0042] and any of the present claims. Applicant further notes that claim 1 still recites the biomaterial being "capable of administering the active agent," and the jacket "permitting passage of molecules of the active agent to and from the core through the jacket to adjacent vascular tissue within the subject." In other words, the active agent is contained in the reservoir (lines 3-4 of amended claim 1), the biomaterial is in communication with the reservoir (lines 5-6 of amended claim 1), and the active agent passes from the core of the biomaterial to adjacent vascular tissue via the jacket (lines 15-18 of amended claim 1). Therefore, the device recited in claim 1 is still delivering the active agent from the biomaterial. The Office's reliance on paragraph [0042] to reject the present claims as lacking §112 support is ultimately without any merit.

### Conclusion

Applicant expressly reserves all rights and arguments with respect to distinctions not explicitly noted herein. In addition, to the extent that the amendments constitute a narrowing of the claims, such narrowing of the claims should not be construed as an admission as to the merits of the prior rejections. Indeed, Applicant traverses the rejections and preserves all rights and arguments. To the extent that any particular statement or argument by the Office in the pending Office Action has not been explicitly addressed herein, the same should not be construed as an acquiescence or admission by the Applicant that such statements or arguments by the Office are accurate or proper.

Based on the foregoing, all pending claims are in a condition for allowance. Accordingly, Applicant respectfully requests reconsideration and an early notice of allowance. Should the

Serial No. 10/736,421

Examiner wish to discuss the amendments or arguments made herein, Applicant invites the Examiner to contact the undersigned at (513) 369-4811 or via e-mail at [aulmer@fbtlaw.com](mailto:aulmer@fbtlaw.com).

The Commissioner for Patents is hereby authorized to charge any deficiency, including any fees required for an extension of time not already paid for or any other required fees not already paid for, or to credit any overpayment of fees, to Frost Brown Todd LLC Deposit Account No. 06-2226.

Respectfully Submitted,



Andrew B. Ulmer (Reg. No. 57,003)

FROST BROWN TODD LLC  
2200 PNC Center  
201 East Fifth Street  
Cincinnati, Ohio 45202  
(513) 369-4811  
[aulmer@fbtlaw.com](mailto:aulmer@fbtlaw.com)

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